Bertilimumab Granted Orphan Drug Designation for the Treatment of Bullous Pemphigoid

ENGLWOOD CLIFFS, N.J., Aug. 20, 2018 (GLOBE NEWSWIRE) -- Immune Pharmaceuticals, Inc. (OTCQB: IMNP) (“Immune” or the “Company”), a biopharmaceutical company developing novel therapeutic agents for the treatment of immunologic and inflammatory diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to bertilimumab for the treatment of bullous pemphigoid (BP).

“We are incredibly gratified that bertilimumab has received Orphan Drug Designation for the treatment of bullous pemphigoid from the FDA and believe this designation, coupled with the recent positive opinion from the EMA’s Committee for Orphan Medicinal Products represent a significant regulatory milestone for bertilimumab,” commented Immune’s Chief Medical and Operating Officer, Tony Fiorino, MD, PhD. “We are focused on putting all of the manufacturing and regulatory pieces in place to launch a pivotal phase 2/3 study of bertilimumab in bullous pemphigoid next year.”

The FDA Orphan Drug Designation program provides a special status to drugs and biologics intended to treat, diagnose or prevent diseases and disorders that affect fewer than 200,000 people in the U.S. This designation provides for a seven-year marketing exclusivity period, as well as certain incentives, including federal grants, tax credits and a waiver of PDUFA filing fees.

About Immune Pharmaceuticals, Inc.

Immune Pharmaceuticals Inc. is a biopharmaceutical company developing novel therapeutic agents for the treatment of immunologic and inflammatory diseases. Immune’s lead program, bertilimumab, is a first-in-class, fully human monoclonal antibody that targets and lowers levels of eotaxin-1, a chemokine that plays a role in immune responses and attracts eosinophils to the site of inflammation. By neutralizing eotaxin-1, bertilimumab may prevent the migration of eosinophils and other cells, thus helping to relieve associated inflammatory conditions. Currently, Immune is conducting two phase 2 clinical trials to test bertilimumab in patients suffering from bullous pemphigoid and ulcerative colitis, respectively. Bertilimumab may have application in other diseases, including atopic dermatitis, immune and inflammatory hepatitis, and asthma.

Safe Harbor Statements Regarding Forward Looking Statements

The statements in this news release made by representatives of Immune relating to matters that are not historical facts, including without limitation, those regarding future...
performance or financial results, the timing or potential outcomes of research collaborations or clinical trials, any market that might develop for any of Immune's product candidates and the sufficiency of Immune's cash and other capital resources, the continued development by Immune of bertilimumab are forward-looking statements that involve risks and uncertainties, including, but not limited to, the likelihood that actual performance or results could materially differ, that future research will prove successful, the likelihood that any product in the research pipeline will receive regulatory approval in the U.S. or abroad, or Immune's ability to fund such efforts with or without partners. Immune undertakes no obligation to update any of these statements. In addition, there can be no assurance that Immune will be able to reduce expenses, capitalize on strategic alternatives, develop its assets, and generate value for shareholders. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as to the date hereof. Accordingly, any forward-looking statements should be read in conjunction with the additional risks and uncertainties detailed in Immune's filings with the Securities and Exchange Commission, including those discussed in Immune's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and periodic reports filed on Form 8-K.

**Investor Contact:**

Investors@immunepharma.com

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